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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,660	06/27/2003	Karla Weaver	10123/00201	6994

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EXAMINER

DEAK, LESLIE R

ART UNIT PAPER NUMBER

3761

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/608,660

Applicant(s)

WEAVER ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4-12,15,16 and 18-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-12,15-16,18-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. While the drawings are acceptable for examination, they are objected to because they feature photographs (see FIG 2) and extraneous markings (especially FIG 7). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required should the application go to allowance. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4-6, 8, 15, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,991,745 to Brown.

In the specification and figures, Brown discloses the apparatus as claimed by applicant. In particular, Brown discloses a bidirectional fluid control valve. The valve 1 is constructed of a flat disc-shaped pad made of a flexible plastic such as silicone (see column 5, lines 35-45, column 6, lines 14-15, FIGS 3-5). The disc comprises a slit 8 that creates mating slit edges or flaps 47 and 48 that closely abut one another when in the closed position (see column 6, lines 6, lines 24-37). The valve further comprises generally square-shaped discrete ribs 7 that surround the linear slit and selectively stiffen the center valve area to control the flexure thereof, acting as a biasing member (see column 6, lines 37-63).

With regard to applicant's recitation of the opening and closing of the valve at particular pressures, such limitations are held by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,991,745 to Brown, as applied above.

In the specification and figures, Brown discloses the apparatus substantially as claimed by applicant with the exception of the threshold pressure of the valve. Brown specifically discloses that the physical characteristics of the valve may be varied in accordance with the desired threshold pressure (see column 6, lines 64-67, column 7, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the valve to respond to a desired threshold pressure as claimed by applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,991,745 to Brown, as applied above, in view of US 6,621,557 to Cushman et al.

In the specification and figures, Brown discloses the apparatus substantially as claimed by applicant with the exception of a biasing member comprising a wire. Cushman discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of the bore 38 holding the valve in place and restraining the resilient material in a closed position.

Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to use a wire as a biasing member around the slit of the valve

disclosed by Brown in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman.

7. Claims 9-12, 16, 18, 22-27, 30, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,810,789 to Powers in view of US 4,991,745 to Brown.

In the specification and figures, Powers discloses the apparatus substantially as claimed by applicant. In particular, Powers discloses a dual-lumen catheter with slit valves associated with each lumen of the catheter, thereby providing separate valving and fluid flow operation for each lumen (see column 5, lines 27-31). Providing additional flexible members, moveable elements, and biasing members is simply duplicating the single-lumen valve in the Brown device. Powers further discloses that the catheter system is implanted in a patient and allows external access to the fluid flowing through the catheter (see columns 5-6).

Powers fails to disclose that the valve is disc-shaped and comprises a biasing member that maintains the valve in a closed position. Brown discloses a disc-shaped slit valve with generally square-shaped discrete ribs 7 that surround the linear slit and selectively stiffen the center valve area to control the flexure thereof, acting as a biasing member (see Brown column 6, lines 37-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the biasing member disclosed by Brown to the catheter slit valve disclosed by Powers in order to control the flexure of the flat disc-shaped valve, as taught by Brown.

With regard to claim 11, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to

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so perform. See MPEP § 2106. Furthermore, the catheter system disclosed by Powers is capable of dispensing or withdrawing fluid to and from the patient, and is capable of performing as claimed by applicant.

With regard to applicant's recitation of the opening and closing of the valve at particular pressures, such limitations are held by the Examiner to be a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

With regard to applicant's claims 22-27 drawn to the number and arrangement of the biasing members and slits, such variations on the prior art are considered to be obvious to one of ordinary skill in the art. It has been held that mere duplication or rearrangement of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04.

With regard to claims 30 and 32, Brown specifically discloses that the physical characteristics of the valve may be varied in accordance with the desired threshold pressure (see column 6, lines 64-67, column 7, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the valve to respond to a desired threshold pressure as claimed by applicant, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See MPEP § 2144.05.

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8. Claims 19-21 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,810,789 to Powers in view of US 4,991,745 to Brown, as applied above, in view of US 6,621,557 to Cushman et al.

In the specification and figures, Powers and Brown disclose the apparatus substantially as claimed by applicant with the exception of a biasing member comprising a wire. Cushman discloses a disk-shaped resilient slit valve with wire 46 and shoulder end of the bore 38 holding the valve in place and restraining the resilient material in a closed position.

Therefore, it would have been ordinary to one having ordinary skill in the art at the time of invention to use a wire as a biasing member around the slit of the valve disclosed by Brown in order to restrain the resilient material, maintaining a closed valve, as taught by Cushman.

### ***Response to Arguments***

9. Applicant's arguments filed 19 December 2005 have been entered and considered.

10. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:



- a. US 5,030,210 Alchas
- i. Catheter with slit valve

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

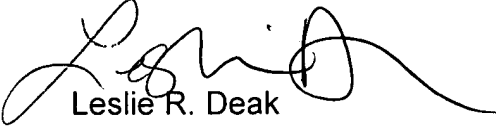
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**PATRICIA BIANCO**  
**PRIMARY EXAMINER**

*3/2/06*

  
Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
27 February 2006